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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/780,953 | 02/09/2001 | Manikkam Suthanthiran | 955-3P/CON | 1712 |

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EXAMINER

HOLLERAN, ANNE L

ART UNIT PAPER NUMBER

1642

DATE MAILED: 12/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/780,953

Applicant(s)

SUTHANTHIRAN ET AL.

Examiner

Anne Holleran

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-20,26,28,29 and 32-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-25,27,30 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The response to the restriction requirement, filed Aug. 20, 2002, electing group II, and species TGF-beta antibody is acknowledged. Because Applicant did not specifically point to errors in the restriction requirement, the response is treated as an election without traverse.
2. Claims 1-35 are pending. Claims 1-20 and 32-35, drawn to non-elected inventions, are withdrawn from consideration. Claims 26, 28 and 29 do not appear to be readable on the elected species and are withdrawn from consideration.
3. Claims 21-25, 27, 30 and 31 are examined on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 21-23 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchinson (Hutchinson, Rev. in Immunogenetics, 1: 323-333, 1999).

Claims 21-31 and 30 are drawn to compositions comprising a TGF-beta antagonist and an immunosuppressive agent. The immunosuppressive agent may be cyclosporine.

Hutchinson teaches that nephrotoxicity and rejection of transplants is associated with high levels of TGF-beta1 (page 328). Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have made a composition that comprised of an anti-TGF beta1 antibody and an immunosuppressive agent such as cyclosporine that is often use in transplant patients.

5. Claims 21-23 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ader (Ader, Curr. Opin Nephrol. Hypertens., 7: 539-545, 1998) in view of Hutichison (supra).

Ader teaches that FK-506 causes nephrotoxicity in transplant patients. As Hutchinson teaches that nephrotoxicity is probably mediated by TGF beta1, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have made a composition that comprised an anti-TGF beta1 antibody and an immunosuppressive agent such as FK-506.

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6. Claims 21-25, 27 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Novak (Novak, Nature Medicine, 5(4): 382, 1999, April) in view of Ohmori (Experimental Cell Research, 245: 350-359, 1998).

Novak teaches that transplant patients receiving immunosuppressants (cyclosporine) are more susceptible to cancer, and teaches that cyclosporin actually promotes tumor progression directly, and that the mechanism is mediated by TGF beta. Ohmori teaches the use of anti-TGF antibodies in the treatment of cancer. Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have made a composition that comprises an anti-TGF beta1 antibody and an immunosuppressive agent such as cyclosporine.

Conclusion

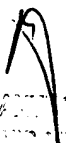
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
December 16, 2002


ANNE L. HOLLERAN
PATENT EXAMINER
TECHNICAL STAFF